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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,173	01/28/2004	John E. Ahern	B0410/7283D1	4427
22832	7590	08/12/2004		
KIRKPATRICK & LOCKHART LLP 75 STATE STREET BOSTON, MA 02109-1808			EXAMINER JACKSON, SUZETTE JAMIE	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,173

Applicant(s)

AHERN, JOHN E.

Examiner

Suzette J Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment dated 6/24/04 has been received in application serial number 10/766,173. Claims 28-31 and 33 have been canceled.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-6, 13, 17-20, 22-27 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Gambale et al. 6,432,126. Gambale et al. discloses the invention as claimed noting figures 1-9 comprising: An implant for treating biological tissue with a therapeutic material associated with a scaffold structure that is implantable within tissue; wherein the scaffold has an interior chamber (14) with at least one opening (20) wherein the therapeutic material is associated with the interior of the scaffold; an exterior surface wherein the therapeutic material is associated with the exterior surface; wherein the therapeutic material defines a plurality of cells or tissue; (see col. 2, lines 44-45 and lines 66-67; col. 3, lines 36-58; col. 4, lines 12-19, lines 38-39); wherein the scaffold

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comprises a coil body (see figure.6b); a mesh tube, porous pellet (see figures 8a-9b); wherein the scaffold can be made of many materials including stainless steel, or biodegradable polymer (see col. 7, lines 37-40).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7-11, 16, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al. in view of Cafferata 6,689,121. Gambale et al. has been disclosed above however Gambale et al. does not specify the phrase *therapeutic material suspended in a liquid* and while Gambale et al. does disclose that therapeutic agents can range from cells, to blood to drugs, they are not specify the therapies. Cafferata teaches a device for treating ischemia, which utilizes therapies such as precursor cells, stem cells, cardiomyocytes, DNA and skeletal myoblast (see col. 3, lines51-55; col. 4 lines 1-5; claim 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the therapies as taught by Cafferata in the device of Gambale et al. because they all aid in the promotion of angiogenesis and this listing of drugs are just a narrow range of drugs well known for there therapeutic

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properties. It is also obvious that nitinol is a shape memory material and Gambale et al. states that shape memory materials can be utilized to form the scaffold device. It is also obvious to one having ordinary skill in the art that the therapies of Gambale et al. are in a liquid suspension because Gambale states in col. 6 to 7, lines 61-67; 1-3 that the angiogenic substance may be delivered into the capsule with a hypodermic need and syringe...rendering it obvious that the substance is in some type of liquid suspension and delivered after implantation.

6. Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al. in view of Slepian 5,575,815. Gambale et al. has been disclosed above however Gambale et al. does not specify joining the therapeutic material to the scaffold by an adhesive or that the materials is maintained in a gel form. Slepian et al. teaches local polymeric gel therapy and drug adhesives. It would have been obvious to one having ordinary skill in the art at the time the invention was made to associate the therapeutic material via adhesive or maintain the material in a gel form, because the tacky characteristics would provide good adhesion to the device without adding additional structural bulk to the implant.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-27 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,719,805. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to one having ordinary skill in the art that the applicant's claims merely re-word the subject matter in a broader context..

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tartaglia et al. 5,637,813 and Martinson et al. (*vascularization of implants*) 5,569,462 show related material.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

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11. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read "Suzette J. Jackson", followed by a long horizontal flourish line.

Suzette J. Jackson
11 August 2004